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EXAMINER	
NIEBAUER, RONALD T	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,126	DOUGLAS ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-50* is/are pending in the application.

4a) Of the above claim(s) *25-37,39-44 and 46-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38,45,49-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendments and arguments filed 10/27/08 and 2/23/09 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed is herein withdrawn.

As noted previously, Group III (claims 38,41-43,45 and 47) and the species of SEQ ID NO:74 (claim 45(i) GWRTLLKKAEVKTVGKLALKHYL) have been elected. Claims 1-24 were previously cancelled.

Although unclear claims 38,49-50 as amended have been interpreted as falling within the scope of Group III.

As discussed in the previous office action, the elected species was found in the prior art. Further, due to the amendments to claim 38 on 10/27/08 an updated search was performed and new rejections appear below. In accord with section 803.02 of the MPEP the claims have been examined fully with respect to the elected species and claims to the nonelected species are withdrawn from further consideration.

Claims 25-37,39-40,44,46,48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 41-43,47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claims 38,45,49-50 are under consideration.

Priority

As discussed in the previous office action, claim 45 is not adequately supported by Application No. 60/404,922. Further, it is noted that since claims 38,49-50 have been amended, the date used for searching for prior art of those claims are discussed under the 112 1st 'New Matter' section.

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/404,922 (8/22/02), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

In the instant case, claim 45 recites a variety of amino acid sequences.

Lack of Ipsis Verbis Support

Application No. 60/404,922 (8/22/02) is void of support for all of the sequences recited in claim 45. It is noted that Table 4 of 60/404,922 provides support for the peptides of claim 45(a)-(p). However, 60/404,922 is void of literal support for the peptides of claims 45(q)-(az). In particular the sequences of the peptides of claims 45(q)-(az) are not recited in the specification, drawings, or tables of 60/404,922.

Lack of Implicit or Inherent Support

Section 2163 of the MPEP states: 'While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure'.

Although the above statement is with respect to new claim limitations, the analysis is similar in determining conditions for receiving the benefit of an earlier filing date.

As discussed above, Table 4 of 60/404,922 provides support for the peptides of claim 45(a)-(p), However, such Table would not lead one to all of the other sequences recited in claim 45. The specification of 60/404,922 (page 1 lines 16-27) recites a number of antimicrobial peptides. However, the specific peptides of claims 45(q)-(az) are not recited in the specification. As such, one would not conclude that Application No. 60/404,922 provides adequate support for the instant claims.

It is noted that section 706.02 VI D of the MPEP sets forth the method to determine the effective filing date. In particular, 'If the application properly claims benefit under 35 U.S.C. 119(e) to a provisional application, the effective filing date is the filing date of the provisional application for any claims which are fully supported under the first paragraph of 35

U.S.C. 112 by the provisional application.'. In the instant case, claim 45 is not fully supported by the provisional Application No. 60/404,922. As such, claim 45 does not receive the benefit of the provisional application. It is noted that claims are either fully supported or not fully supported. In other words, claims are not treated as 'supported in part' even though one particular element may be supported in the provisional application. Since PCT/CA03/01323 (8/22/03) provides support, for example in claim 21, for claim 45 of the instant invention, the priority date used for searching for prior art for claim 45 of the instant invention is 8/22/03. It is noted that claims can not be listed as supported in part. However, claims can be amended to be drawn to peptides that are fully supported and the claims as a whole would receive the benefit of 60/404,922 as appropriate.

Response to Arguments – Priority

Applicants argue that claim 45 is free of the cited art and under the 102a rejection argue that the Patrzykat reference is the applicants own publication.

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive.

As discussed in the 102a rejection, claim 45 is not free of the prior art. MPEP section 2132 III expressly states:

"The term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." "

In the instant case, the Patrzykat reference is by Patrzykat, Gallant, Seo, Pytyck, and Douglas. However, the instant inventors are Douglas, Gallant, and Patrzykat. Thus, for example, Seo and

Pytyck are 'others'. Further, whether or not Patrzykat reference is the applicants own publication does not specifically address the priority issues.

Claim Rejections - 35 USC § 112

The 112 2nd rejection is necessitated by applicants amendments.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38,49-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 (and dependent claims 49-50) refer to an isolated pleurocidin or hepcidin polypeptide that is not found in winter flounder. It is noted that the instant specification provides no special definition for the term 'pleurocidin'. The specification states that pleurocidin is from the winter flounder (page 1 line 19) and refers to the Cole et al reference (JBC 1997 272(18) 12008-12013 as cited in the IDS 7/20/06). Cole expressly teach (abstract) that a specific 25 residue peptide from winter flounder was isolated and named 'pleurocidin'. Thus, Cole teach that the term 'pleurocidin' refers to a single specific peptide that is from winter flounder. However, the instant claims state that pleurocidin, for example, is not found in the winter flounder. Such statement is contradictory to the express teachings of Cole and also the instant specification (page 1 line 19). It is noted that Cole expressly teaches that the name 'pleurocidin' is a term for a specific protein from winter flounder (abstract), not a genus or family of proteins. Although the instant specification makes reference to pleurocidin-like peptides, pleurocidin-like is not the

equivalent of pleurocidin. As such, the claims are confusing because the claims are contradictory because they refer to 'pleurocidin' which is a term of art (see Cole) that refers to a specific peptide from winter flounder, but then go on to state that the peptide is not found in winter flounder. It is unclear how a peptide is found in winter flounder while at the same time not found in winter flounder.

Claims 38,49-50 were previously rejected under 112 1st written description. Since the claims have been amended an updated rejection appears below.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38,49-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow

> persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 38,49-50 are drawn to polypeptides. Although unclear (see 112 2nd) for purposes of examination since a single peptide can not be found in winter flounder while at the same time not be found in winter flounder, claims 38,49-50 have been given the broadest reasonable interpretation such that they are drawn to pleurocidin as well as any other peptide that shares any features (broadly interpreted) of pleurocidin.

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Although unclear (see 112 2nd) for purposes of examination since a single peptide can not be found in winter flounder while at the same time not be found in winter flounder, claims 38,49-50 have been given the broadest reasonable interpretation such that they are drawn to pleurocidin as well as any other peptide that shares any features (broadly interpreted) of pleurocidin.

In the instant case, the polypeptides of claims 38,49-50 are claimed as products by a process. In particular, the process includes obtaining primers and amplifying nucleic acids to obtain polypeptides. However, the recited steps do not impart distinctive structural characteristics to the final product (see MPEP 2113). For example, there could be many polypeptides (which could be structurally and functionally different) that could be identified by the instant claims. Of the many possible polypeptides, no common core structure is taught. For example, the protein source used to obtain a primer does not uniquely define the peptide that is encoded by a nucleic acid amplified by the primer. Primer oligonucleotide sequences can amplify nucleic acids that encode for a wide range of proteins. Further, due to the lack of clarity of the claims, the claims are interpreted to include any peptides that share any features (broadly interpreted) of pleurocidin. Hence, there is substantial variability in the genus. Examples of polypeptides are recited in the claims. However, such examples are not representative of the instant genus.

Since there are a substantial variety of polypeptides possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claims 38,49-50 recite that the peptides are 'antimicrobial peptides'. The specification, page 10-11, discuss general amino acid sequences. It is noted that the elected species, for example, does not fall within the scope of the sequences recited on page 10-11. Further, tables 4 and 11 and the figures (such as 17) recite various antimicrobial sequences. However, there is no correlation provided between structure and function. There is no teaching in the specification

regarding which and/or how many amino acids can be substituted or deleted to obtain an antimicrobial peptide. In particular, no common structural core is taught for the polypeptides.

Although claim 38 recites that the peptide is made by a process in which it is capable of being amplified by PCR with particular primers, such a description does not provide any common attributes or characteristics that identify the antimicrobial peptides of the instant invention.

Taken together, there are no common attributes or characteristics that identify the antimicrobial peptides of the instant claims. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention:

The specification (specifically page 23) describes the synthesis of polypeptides. Figures 13-15 show the impact of particular peptides (NRC-15, NRC-13, NRC-12, compare Table 4) against a specific bacteria. However, the method of making such peptides does not support the scope of the instant claims.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 38,49-50 is/are broad and generic, with respect to all possible polypeptides encompassed by the claims. The possible structural variations are numerous. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the polypeptides beyond those polypeptides

specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of polypeptides identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of polypeptides embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Response to Arguments – Written Description

Claims 38,49-50 were previously rejected under 112 1st written description. Since the claims have been amended an updated rejection appears above. Applicants arguments will be considered with respect to the instant rejections.

Applicants argue that the preamble of claim 38 has been amended.

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive.

Although Applicants argue that the preamble of claim 38 has been amended, the claim amendment has rendered the claims unclear (see 112 2nd). As such, in accord with section 2111

of the MPEP the claims are given the broadest reasonable interpretation. As discussed above, the recited steps of the claims do not impart distinctive structural characteristics to the final product (see MPEP 2113).

This rejection is necessitated by applicants amendments.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38,49-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 38 (and dependent claims 49-50) have been amended to recite 'an isolated pleurocidin or hepcidin polypeptide that is not found in winter flounder...'.

As discussed above (see 112 2nd) the claim amendment renders the claims unclear.

Lack of Ipsis Verbis Support

The specification is void of any literal support for pleurocidin that is not found in winter flounder.

Lack of Implicit or Inherent Support

Section 2163 of the MPEP states: 'While there is no in haec verba requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure'.

The specification states that pleurocidin is from the winter flounder (page 1 line 19) and refers to the Cole et al reference (JBC 1997 272(18) 12008-12013 as cited in the IDS 7/20/06). Cole expressly teach (abstract) that a specific 25 residue peptide from winter flounder was isolated and named 'pleurocidin'. Thus, Cole teach that the term 'pleurocidin' refers to a single specific peptide that is from winter flounder. However, the instant claims state that pleurocidin, for example, is not found in the winter flounder.

Since Cole teach that 'pleurocidin' is the name given to a specific peptide that is from winter flounder, pleurocidin is from winter flounder. As such, pleurocidin that is not from winter flounder is not supported by the instant specification. In other words, the claims as amended are contradictory to the use of the term 'pleurocidin' as set forth in Cole. It is noted that Cole expressly teaches that the name 'pleurocidin' is a term for a specific protein from winter flounder (abstract), not a genus or family of proteins. Although the instant specification makes reference to pleurocidin-like peptides, pleurocidin-like is not the equivalent of pleurocidin. A discussion of pleurocidin which is from winter flounder would not lead one to pleurocidin that is not found in winter flounder. One would not conclude that there is support for pleurocidin not found in winter flounder. Hence, it can not be said that the specification provides support for pleurocidin not found in winter flounder.

Claims 38,49-50 represent new matter and are not supported by the provisional application 60/404,922 dated 8/22/02 nor the PCT dated 8/22/03 nor the instant application dated 2/18/05.

Claim Rejections - 35 USC § 102

Claim 45 was previously rejected under 102a and the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 45 is rejected under 35 U.S.C. 102(a) as being anticipated by Patrzykat et al. (Antimicrobial Agents and Chemotherapy Aug 2003, v47no8 pages 2464-2470) as evidenced by the wayback machine (http://www.archive.org entry for aac.asm.org (4 pages) and the actual link to aac.asm.org dated Aug 5 2003 (1 page)).

As discussed above, for purposes of searching for prior art the priority date of claim 45 is 8/22/03.

Patrzykat teach the antimicrobial peptide GWRTLLKKAEVKTVGKLALKHYL (abstract) which is identical to the peptide recited in claim 45(i) (SEQ ID NO:74) (i.e. the elected species).

As evidence that the August 2003 article is proper 'prior art' the entry from the wayback machine shows that the aac.asm web site (the publisher of the Patrzykat et al. article) was

updated on August 5, 2003 (see attached). The August 5, 2003 entry on the aac.asm web site (see attached) reveals that the August 2003 issue was posted and publicly accessible as of August 5, 2003. As such, the wayback machine is merely cited to show that Patrzykat et al. is prior art.

Response to Arguments – 102a rejection

Applicants argue that the Patrzykat reference is the applicants own publication.

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive.

MPEP section 2132 III expressly states:

"The term "others" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by others." "

In the instant case, the Patrzykat reference is by Patrzykat, Gallant, Seo, Pytyck, and Douglas. However, the instant inventors are Douglas, Gallant, and Patrzykat. Thus, for example, Seo and Pytyck are 'others'. As such, Patrzykat et al. is a proper 102a reference.

Claims 38,49-50 were previously rejected under 102b. Since the claims have been amended an updated rejection appears below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38,49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (as disclosed in IDS 7/20/06 (entry #10) although IDS erroneously lists publication date as 2000, the correct publication date is March 2001 (see entry #14)).

Claims 38,49-50 are directed to a polypeptide that is encoded by a nucleic acid sequence that is identified by a particular process. For product by process claims section 2113 of the Manual of Patent Examination Procedure states:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Although unclear (see 112 2nd) for purposes of examination since a single peptide can not be found in winter flounder while at the same time not be found in winter flounder, claims 38,49-50 have been given the broadest reasonable interpretation such that they are drawn to pleurocidin as well as any other peptide that shares any features (broadly interpreted) of pleurocidin.

Douglas teach pleurocidin-like antimicrobial peptides (abstract, Figure 4). Douglas also refer to the known pleurocidin peptide (page 142 first paragraph). As such, Douglas teach both the known pleurocidin peptide and pleurocidin-like peptides which have been interpreted to read on instant claims 38,49-50.

Response to Arguments – 102b Douglas

Claims 38,49-50 were previously rejected under 102b. Since the claims have been amended an updated rejection appears below. Applicants arguments will be considered to the extent that that apply to the instant rejection.

Applicants argue that claim 38 has been amended and the peptides of Douglas are limited to winter flounder.

Applicant's arguments filed 10/27/08 have been fully considered but they are not persuasive.

Although Applicants argue that claim 38 has been amended, the claim amendment has rendered the claims unclear (see 112 2nd). As such, in accord with section 2111 of the MPEP the claims are given the broadest reasonable interpretation. As discussed above, since a single peptide can not be found in winter flounder while at the same time not be found in winter flounder, claims 38,49-50 have been given the broadest reasonable interpretation such that they are drawn to pleurocidin as well as any other peptide that shares any features (broadly interpreted) of pleurocidin. Douglas teach the known pleurocidin peptide (page 142 first paragraph) as well as pleurocidin-like antimicrobial peptides (abstract, Figure 4).

This rejection is necessitated by applicants amendments.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38,49-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Patrzykat et al. (Antimicrobial Agents and Chemotherapy Aug 2003, v47no8 pages 2464-2470 as cited previously)

Patrzykat teach the antimicrobial peptide GWRTLLKKAEVKTVGKLALKHYL (abstract) which is derived from the American plaice.

Claims 38,49-50 are directed to a polypeptide that is encoded by a nucleic acid sequence that is identified by a particular process. For product by process claims section 2113 of the Manual of Patent Examination Procedure states:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Although unclear (see 112 2nd) for purposes of examination since a single peptide can not be found in winter flounder while at the same time not be found in winter flounder, claims 38,49-50 have been given the broadest reasonable interpretation such that they are drawn to pleurocidin as well as any other peptide that shares any features (broadly interpreted) of pleurocidin. Since the peptide described by Patrzykat is an antimicrobial peptide and appears to be made by a similar method as claimed, the burden is on the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product (see MPEP section 2113 3rd paragraph section entitled 'Once a product appearing to be substantially identical is found and a 35 USC 102/103 rejection made, the burden shifts to applicant to show an unobvious difference').

As discussed above (112 1st new matter) claims 38,49-50 represent new matter and are not supported by the provisional application 60/404,922 dated 8/22/02 nor the PCT dated 8/22/03 nor the instant application dated 2/18/05. Thus, Patrzykat (August 2003) is an appropriate 102b reference for claims 38,49-50.

Conclusion

In the reply filed filed 10/27/08 applicant amended claims 38,49-50 which necessitated any new rejections in this office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Niebauer/
Examiner, Art Unit 1654